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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,880	07/28/2003	Neal L. Eigler	CEDAR.001A	3872

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EXAMINER	
RYCKMAN, MELISSA K	

ART UNIT	PAPER NUMBER
3734	

NOTIFICATION DATE	DELIVERY MODE
09/21/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/628,880	EIGLER ET AL.	
	Examiner	Art Unit	
	Melissa Ryckman	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-34 and 78-103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-34 and 78-103* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/18/07 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-34 and 78-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original disclosure does not disclose wherein the anchor zone is configured to bend at least about 90 degrees, in the specification, the drawings or the claims. The only mention of the anchor zone in the specification is in paragraphs 72-73, "the distal end includes an anchor zone," "In general, the anchor zone is of a sufficient length distally of the procedure zone, to enable orientation and anchoring of the catheter within the vasculature. In one

embodiment, the minimum length of the anchor zone is at least about 3 cm. In some embodiments, the anchor zone is at least about 5 cm, and in certain applications, at least about 10 cm in length." No where does it disclose that the anchor zone is capable of bending, nor to what extent. The original document does not disclose the anchor zone "having sufficient rigidity to stabilize the tissue manipulator."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27-29, 31-34, 78-84, 86-91,102, and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuehn et al. (US 6165183) in view of Cribier et al. (US 4777951).

Kuehn teaches a catheter capable of accessing the heart and engaging a heart valve comprising:

- an elongate flexible body (108) having a proximal and a distal end; an anchor zone (441) on a distal portion of the body, that has sufficient rigidity to stabilize the tissue manipulator (inherently 440 has sufficient rigidity for the device to work); and at least one tissue manipulator (440) carried by the flexible body proximally of the anchor zone (fig. 20)
- a first and a second tissue manipulator (fig. 20).

- wherein the tissue manipulator is moveable between an axial orientation for transluminal navigation and an inclined orientation for manipulating tissue.
- wherein the first tissue manipulator (440) comprises a tissue grasper for grasping a heart valve leaflet (122).
- at least a first component (440), which is axially moveable with respect to a second component (Column 9, proximate lines 57-64)
- the catheter having a length sufficient to reach the heart from a femoral vein access
- the first and second tissue manipulators (440) are asymmetric (the graspers are not symmetric when cut in half between the proximal and distal end), the first tissue manipulator is longer than the second tissue manipulator (see Fig. 20).

Kuehn fails to teach wherein the anchor zone is elongate and flexible and configured to bend at least 90 degrees to extend at least into an anatomical region adjoining the heart valve. Cribier teaches an interventional catheter for accessing the heart wherein the distal most portion is an elongate flexible anchor zone (20) which is at least about 5cm and configured to bend at least 90 degrees in order to stabilize the device such that it rests in the heart and provides a non-traumatic surface on the heart lining. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kuehn with the anchor zone of Cribier in order to stabilize the device such that it rests in the heart and provides a non-traumatic surface on the heart lining.

The anchor zone of Cribier is further configured to extend from a left atrium through a mitral valve and into a left ventricular outflow tract, extend through a left ventricular outflow tract into an aorta, through a tricuspid valve and into a right ventricular outflow tract, through a right ventricular outflow tract into a pulmonary artery.

Claims 27, 92-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuehn et al. (US 6165183) in view of Cribier et al. (US 4777951).

Kuehn teaches a catheter capable of accessing the heart and engaging a heart valve comprising:

- an elongate flexible body (126) having a proximal and a distal end; an anchor zone (portion distal to 500 and 502, Fig. 23) on a distal portion of the body, that has sufficient rigidity to stabilize the tissue manipulator (inherently portion distal to 500 and 502 has sufficient rigidity for the device to work); and a first and second tissue manipulator (500 and 502) carried by the flexible body proximally of the anchor zone (fig. 20).
- the elongate flexible body comprises a fastening material carried on the flexible body for suturing two leaflets together (506).
- there is at least one needle capturing device coupled with an end of the fastening material (510 is needle).
- The fastening material (510) is at least partially housed within the tissue manipulator (508 encompasses the tissue manipulator, 504, therefore it is considered within the tissue manipulator).

- The first (500) and second (502) tissue manipulators are asymmetric (Fig. 23), the first manipulator (500) is longer than the second manipulator (502, Fig. 23).
- The first tissue manipulator (500) comprises a receptacle located within the first tissue manipulator (hole in 500) receives a first fixating member (122, Fig. 23).
- The second tissue manipulator (502) comprises a receptacle located within the first tissue manipulator (hole in 502) receives a first fixating member (124, Fig. 23).
- A first end of a fastening material (506) is coupled with the first receptacle (hole in 500) and a second end of the fastening material (proximal end of 506) is coupled with the second receptacle (col. 10, ll. 35, these are coupled to each other because once the fastening material is delivered the first and second receptacles release the leaflets, the word coupled is interpreted by the examiner to be a related pair, this does not mean they are touching).
- The fastening material (506) is at least partially located distal of the tissue manipulator (col. 10, ll. 35, after the lumen 504 is withdrawn the fastening material is distal to the tissue manipulator).

Kuehn fails to teach wherein the anchor zone is elongate and flexible and configured to bend at least 90 degrees to extend at least into an anatomical region adjoining the heart valve. Cribier teaches an interventional catheter for accessing the heart wherein the distal most portion is an elongate flexible anchor zone (20) which is at least about 5cm and configured to bend at least 90 degrees in order to stabilize the

device such that it rests in the heart and provides a non-traumatic surface on the heart lining. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kuehn with the anchor zone of Cribier in order to stabilize the device such that it rests in the heart and provides a non-traumatic surface on the heart lining.

The anchor zone of Cribier is further configured to extend from a left atrium through a mitral valve and into a left ventricular outflow tract, extend through a left ventricular outflow tract into an aorta, through a tricuspid valve and into a right ventricular outflow tract, through a right ventricular outflow tract into a pulmonary artery.

Claims 30 and 85 rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kuehn and Cribier and further as a matter of design choice. The combination of Kuehn and Cribier teaches all limitations of preceding dependent claims 27 and 82 as described previously, but fails to disclose wherein the length of anchor zone is at least about 10cm. Since applicant has not disclosed that each respective anchor zone length provides any advantage over another, and it appears that the anchor zone of the combination of Kuehn and Cribier performs the task of positioning the device at the desired location equally well as that of the application, it would have been obvious to one of ordinary skill in the art at the time the invention was made to disclose the length of the anchor zone of the combination of Kuehn and Cribier as at least 10cm since it has been held that where the general conditions of a claim are

disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105, USPQ 233.

Response to Arguments

Applicant's arguments filed 6/18/07 have been fully considered but they are not persuasive. The applicant generally argues the following:

- Fig. 3 in the current application shows the anchor zone bending at least about 90 degrees.
- Kuehn teaches away from an anchor zone, a distally placed structure that is useful for positioning or orienting the device.
- The tip portion of Cribier is incapable of acting as an anchor zone.

The examiner respectfully disagrees with the applicant, Fig. 3 in the current application shows the catheter bending, it does not show the anchor zone bending. Kuehn does not teach away from an anchor zone (as 440 is an anchor) or a portion distal of the anchor zone (441, Fig. 21). Cribier is capable of acting as an anchor zone, the bend at the distal end of Fig. 1 is capable of acting as an anchor zone.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)-272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR

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SUPERVISORY PATENT EXAMINER